

Keith J. Miller, Esq.  
ROBINSON MILLER LLC  
One Newark Center, 19th Floor  
Newark, NJ 07102  
Telephone: (973) 690-5400  
kmiller@rwmlegal.com

*Attorneys for Plaintiffs Genentech, Inc.,  
Biogen, Inc., and City of Hope*

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

GENENTECH, INC., a Delaware corporation,  
BIOGEN, INC., a Delaware corporation, and  
CITY OF HOPE, a California not-for-profit  
organization,

Plaintiffs,

v.

SANDOZ, INC., a Colorado corporation,  
SANDOZ INTERNATIONAL GMBH, a  
German corporation, and SANDOZ GMBH,  
an Austrian corporation,

Defendants.

Case No.

**COMPLAINT FOR: PATENT  
INFRINGEMENT; DECLARATORY  
RELIEF**

**DEMAND FOR JURY TRIAL**

Pursuant to Local Civil Rule 10.1, the address of Plaintiff Genentech, Inc. (“Genentech”) is 1 DNA Way, South San Francisco, California, 94080. The address of Plaintiff Biogen, Inc. (“Biogen”) is 225 Binney Street, Cambridge, Massachusetts, 02142. The address of Plaintiff City of Hope is 1500 East Duarte Road, Duarte, California, 91010. The address of Defendant Sandoz, Inc. is One Health Plaza, East Hanover, New Jersey, 07936, with another address at 100 College Road West, Princeton, New Jersey, 08540. The address of Defendant Sandoz International GmbH is Industriestrasse 25, 83607 Holzkirchen, Germany. The address of Defendant Sandoz

GmbH is Biochemiestrasse 10, 6250 Kundl, Austria.

Plaintiffs Genentech, Biogen, and City of Hope (collectively, “Plaintiffs”) by their undersigned attorneys, for their Complaint against Defendants allege as follows:

**NATURE OF THIS ACTION**

1. This is an action for patent infringement arising under 28 U.S.C. § 1331 and the United States Patent Act, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2), and an action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, seeking a declaratory judgment of patent infringement.

2. The claims for patent infringement brought in this action are necessitated by Defendants’ stated intent to import, market, and sell in New Jersey and throughout the United States a copy of Genentech and Biogen’s groundbreaking medicinal product, Rituxan®, which aids millions of patients in their fight against debilitating and life-threatening diseases, including blood cancers such as Non-Hodgkin’s Lymphoma and Chronic Lymphocytic Leukemia, as well as Rheumatoid Arthritis and Vasculitis, which are chronic and painful autoimmune diseases. First approved in 1997, Rituxan® is proven to improve both the length and quality of life for patients with these and other diseases and has been recognized internationally for its pioneering effect on patients’ lives and medicine in general.

3. Such benefits and success did not come quickly or easily. Genentech and Biogen invested many years of work and many hundreds of millions of dollars into developing and testing Rituxan® and ensuring that the product is both safe and effective. Those investments include, *inter alia*, years of laborious and expensive clinical trials that were required before medical professionals could use Rituxan® to help their patients—clinical trials on which the U.S. Food and Drug Administration (“FDA”) relied in making Rituxan® the first monoclonal antibody approved for therapeutic use in fighting cancer in the United States.

4. In contrast, Defendants have piggybacked on Plaintiffs’ investments and success and seek to profit from a copied version of Rituxan®. Claiming that their copycat product is “biosimilar” to Rituxan®, Defendants have not borne the expense of conducting their own

clinical trials—instead relying on Genentech and Biogen’s costly and time-consuming proprietary clinical trials—and have applied to the FDA for approval to market and sell that product for the very same therapeutic uses as Rituxan®.

5. Irrespective of whether they are able to secure FDA approval for their copy of Rituxan®, however, Defendants do not have the right to infringe Plaintiffs’ patents. As stated herein, Defendants’ intended activities would unquestionably infringe many of those patents, *none* of which Plaintiffs have licensed to Defendants and *all* of which are valid and enforceable. Plaintiffs bring this action to stop that infringement.

### **PARTIES**

6. Plaintiff Genentech, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, California, 94080.

7. Plaintiff Biogen, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 225 Binney Street, Cambridge, Massachusetts, 02142.

8. Plaintiff City of Hope is a California not-for-profit organization, having its principal place of business at 1500 East Duarte Road, Duarte, California, 91010.

9. Genentech and Biogen, two pioneers of the biotechnology industry, have been discovering, developing, manufacturing, and commercializing innovative therapies to address significant unmet medical needs for more than 40 years. Collectively, they manufacture and commercialize products for a variety of medical conditions, including numerous types of cancer, Rheumatoid Arthritis, Multiple Sclerosis, and many other serious conditions. Genentech and Biogen developed and jointly market Rituxan®, the revolutionary antibody-based medicine at issue in this case.<sup>1</sup>

---

<sup>1</sup> Genentech initially collaborated with IDEC Pharmaceuticals, which subsequently merged with Biogen (forming Biogen-Idem) and later adopted the name Biogen. We use “Biogen” herein for simplicity.

10. Founded in 1913, City of Hope is a leading research hospital that incorporates cutting-edge research into patient care for cancer, diabetes, and other serious diseases.

11. Plaintiffs regularly seek patents on inventions originating from their research and development activities, and each has been issued numerous patents relating to its proprietary technology. Among those patents are several that claim, *inter alia*, the manufacture and use of Rituxan®.

12. Plaintiffs are informed and believe, and on that basis allege, that Defendant Sandoz, Inc. is a corporation organized and existing under the laws of the State of Colorado, having offices at One Health Plaza, East Hanover, New Jersey, 07936, and its principal place of business at 100 College Road West, Princeton, New Jersey, 08540.

13. Plaintiffs are informed and believe, and on that basis allege, that Defendant Sandoz International GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, having its principal place of business at Industriestrasse 25, 83607 Holzkirchen, Germany.

14. Plaintiffs are informed and believe, and on that basis allege, that Defendant Sandoz GmbH is a corporation organized and existing under the laws of the Republic of Austria, having its principal place of business at Biochemiestrasse 10, 6250 Kundl, Austria.

15. Plaintiffs are informed and believe, and on that basis allege, that Sandoz, Inc., Sandoz International GmbH, and Sandoz GmbH (collectively, "Sandoz") operate within a division of Novartis, one of the largest pharmaceutical companies in the world, and are almost entirely dedicated to the development of generic and "biosimilar" products.

#### **JURISDICTION AND VENUE**

16. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* This Court has federal question jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202 because this is a civil action arising under the Patent Act.

17. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b), including because Sandoz, Inc. has committed acts of infringement in and has a regular and

established place of business in New Jersey.

**A. Sandoz, Inc.**

18. Plaintiffs are informed and believe, and on that basis allege, that this Court has personal jurisdiction over Sandoz, Inc. because Sandoz, Inc. has availed itself of the legal protections of the State of New Jersey by, among other things, maintaining its principal place of business in New Jersey, registering to do business in New Jersey, and conducting operations related to the manufacturing, importing, marketing, and/or selling of pharmaceutical drug products in New Jersey.

19. Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Sandoz, Inc. because Sandoz, Inc. has purposefully directed activities at the State of New Jersey and this litigation relates to or arises out of those activities. In particular, Plaintiffs are informed and believe, and on that basis allege, that Sandoz, Inc. has taken the costly, significant step of filing an Abbreviated Biologic License Application (“aBLA”) with the FDA seeking FDA approval of the proposed biosimilar product Rixathon (also referred to by the development code “GP2013”) for the express purposes of marketing, distributing, and selling Rixathon/GP2013 in New Jersey and throughout the United States.

20. Plaintiffs are informed and believe, and on that basis allege, that if and when the FDA approves that aBLA for Rixathon/GP2013, Sandoz, Inc. intends to import, market, distribute, and sell Rixathon/GP2013 in New Jersey and throughout the United States. Moreover, Plaintiffs are informed and believe, and on that basis allege, that Sandoz, Inc. intends to coordinate the importation, marketing, distribution, and sale of Rixathon/GP2013 from New Jersey, where its United States leadership team is based.

21. Plaintiffs are further informed and believe, and on that basis allege, that Sandoz, Inc. has previously submitted to the jurisdiction of this Court and availed itself of the legal protections of the State of New Jersey by asserting claims and not contesting jurisdiction in the United States District Court for the District of New Jersey. *See, e.g., Sandoz Inc. v. Daiichi*

*Sankyo, Inc., et al.*, No. 16-cv-00994 (D.N.J. Feb. 22, 2016); *Immunex Corp., et al. v. Sandoz Inc., et al.*, No. 16-cv-1118, Answer, ¶ 19 (D.N.J. Mar. 21, 2016).

**B. Sandoz International GmbH**

22. Plaintiffs are informed and believe, and on that basis allege, that Sandoz International GmbH has engaged in the foregoing contacts with New Jersey directly and through one or more agent and/or alter ego subsidiaries, including by controlling and directing the conduct of Sandoz, Inc. and by establishing and operating Sandoz, Inc. in order to undertake activities that, if not for Sandoz, Inc., Sandoz International GmbH would have to undertake itself.

23. Plaintiffs are informed and believe, and on that basis allege, that Sandoz International GmbH and its subsidiaries, including Sandoz, Inc., operate within a division of Novartis organized around the manufacture, distribution, marketing, and sale of pharmaceuticals, and particularly generic and biosimilar pharmaceuticals.

24. Plaintiffs are informed and believe, and on that basis allege, that Sandoz operates and holds itself out to the world as one company that, despite its global operations, maintains unitary administration, values, policies, history, and strategy. Indeed, on its website [www.sandoz.com](http://www.sandoz.com), which is copyrighted by “Sandoz International GmbH” and “intended for a global audience,” Sandoz publicly describes itself as a “single global brand.” And, according to the website of Sandoz’s United States operations (headquartered in New Jersey), “the Sandoz brand has been transformed into a global leader in generic pharmaceuticals and biosimilars. Today, as a division of the Novartis Group, we offer approximately 1,000 molecules covering a broad range of therapeutic areas. In 2015, our products reached more than 500 million patients and we aspire to reach one billion.” <https://www.us.sandoz.com/about-us/who-we-are/sandoz-brand>. As yet another example of that unitary administration, on information and belief, Sandoz aggregates and reports (through Novartis) its financial performance on a global, division-wide basis, with individual entities not reporting separate financial data or making separate financial reports to governmental authorities.

25. Plaintiffs are further informed and believe, and on that basis allege, that Sandoz International GmbH exercises control over the Sandoz division and over the Sandoz subsidiaries—including Sandoz, Inc. and with respect to biosimilars—through a global Sandoz Executive Committee. That committee, led by “Division Head” Richard Francis, includes Peter Goldschmidt, whom Sandoz International GmbH lists as the “President of Sandoz US and Head of North America.” <https://www.sandoz.com/about-us/who-we-are/sandoz-leadership>. Mr. Goldschmidt also headlines the “Sandoz US Leadership,” which is “responsible for overseeing the business operations of Sandoz in the US,” and also holds the position of President, Sandoz, Inc. <https://www.us.sandoz.com/about-us/who-we-are/sandoz-us-leadership>.

26. Plaintiffs are further informed and believe, and on that basis allege, that through this global Sandoz Executive Committee, Sandoz International GmbH exercises control and makes and approves significant decisions concerning the manufacture, distribution, marketing, and sale of biosimilars in the United States, including of Sandoz’s proposed Rixathon/GP2013 product. On information and belief, the acts of Sandoz, Inc. complained of herein thus were and will be done, in part, for the benefit of Sandoz International GmbH.

27. For example, on information and belief, Sandoz International GmbH coordinated and directed Sandoz, Inc. to act as its agent in preparing and filing Sandoz’s aBLA for Rixathon/GP2013 and Sandoz International GmbH is actively involved in planning Sandoz, Inc.’s planned importation, marketing, and sale of Rixathon/GP2013. In a press release dated September 12, 2017, issued from Sandoz International GmbH’s Holzkirchen, Germany headquarters, Sandoz announced that the “US Food and Drug Administration (FDA) has accepted its Biologics License Application (BLA)” for Rixathon/GP2013. <https://www.sandoz.com/news/media-releases/sandoz-proposed-biosimilar-rituximab-accepted-review-fda>. That press release included the following quote from Mark Levick, MD PhD (listed as the Global Head of Development, Biopharmaceuticals at Sandoz): “With the FDA acceptance of our regulatory submission for proposed biosimilar rituximab, we plan to deliver patients a high-quality Sandoz biosimilar that, following approval, could help drive healthcare savings and

increase competition, while freeing up resources for and supporting patient access in other areas of cancer care including innovative therapies.” *Id.* On information and belief, Dr. Levick is a Sandoz Senior Vice President based in Sandoz International GmbH’s Holzkirchen, Germany headquarters.

28. In addition, Plaintiffs are informed and believe, and on that basis allege, that Novartis applied for and obtained a registration for at least one trademark with the United States Patent and Trademark Office for the word “Rixathon,” which trademark (i) Novartis holds in the name of Sandoz International GmbH, (ii) Sandoz International GmbH intends to use in commerce in the United States, and (iii) through which Sandoz International GmbH has availed itself of the benefits of United States law.

29. Plaintiffs are informed and believe, and on that basis allege, that Sandoz International GmbH has previously submitted to the jurisdiction of this Court and availed itself of the legal protections of the State of New Jersey by asserting affirmative defenses and not contesting jurisdiction in the United States District Court for the District of New Jersey. *See, e.g., Immunex Corp., et al. v. Sandoz Inc., et al.*, No. 16-cv-1118, Answer, ¶ 30 (D.N.J. Sept. 21, 2016).

30. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Sandoz International GmbH pursuant to Federal Rule of Civil Procedure 4(k)(2) because Sandoz International GmbH has extensive contacts with the United States, including but not limited to the above-described contacts, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Sandoz International GmbH is consistent with the laws of the United States and the United States Constitution.

**C. Sandoz GmbH**

31. Plaintiffs are informed and believe, and on that basis allege, that Sandoz GmbH is part of the Sandoz-branded Novartis division discussed above and a Sandoz entity specifically involved in the manufacturing and distribution of biosimilar pharmaceuticals, including of the

proposed Rixathon/GP2013 biosimilar at issue in this action.

32. Plaintiffs are informed and believe, and on that basis allege, that Sandoz manufactures biosimilars at three locations in Europe, two of which are operated by Sandoz GmbH in Austria. Plaintiffs are further informed and believe, and on that basis allege, that Sandoz manufactures Rixathon/GP2013 at one or both of those Sandoz GmbH facilities and that any Rixathon/GP2013 imported into the United States by Sandoz will originate at one of those Sandoz GmbH facilities.

33. Plaintiffs are informed and believe, and on that basis allege, that Sandoz GmbH collaborates with Sandoz, Inc. to, at a minimum, develop, manufacture, and seek approval for proposed biosimilars, including Rixathon/GP2013. Title 42 U.S.C. § 262(k)(2)(A)(v) requires that any application for a proposed biosimilar product “shall include” information demonstrating that “the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.” On information and belief, the facility at which Sandoz manufactures Rixathon/GP2013 is operated by Sandoz GmbH and Sandoz GmbH collaborated with Sandoz, Inc. in the determination of the necessary requirements for that facility and the preparation of the requisite aBLA submitted by Sandoz, Inc., discussed above, pursuant to which Sandoz intends to import, market, offer for sale, and sell Rixathon/GP2013 in New Jersey and throughout the United States.

34. Plaintiffs are further informed and believe, and on that basis allege, that the acts of Sandoz, Inc. complained of herein were and will be done, in part, for the benefit of Sandoz GmbH, which manufactures and exports the Rixathon/GP2013 product that is the subject of this action.

35. Plaintiffs are informed and believe, and on that basis allege, that Sandoz GmbH has previously submitted to the jurisdiction of this Court and availed itself of the legal protections of the State of New Jersey by asserting affirmative defenses and not contesting jurisdiction in the United States District Court for the District of New Jersey. *See, e.g., Immunex*

*Corp., et al. v. Sandoz Inc., et al.*, No. 16-cv-1118, Answer, ¶ 38 (D.N.J. Oct. 28, 2016).

36. In the alternative, Plaintiffs are further informed and believe, and on that basis allege, that this Court has personal jurisdiction over Sandoz GmbH pursuant to Federal Rule of Civil Procedure 4(k)(2) because Sandoz GmbH has extensive contacts with the United States, including but not limited to the above-described contacts, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Sandoz GmbH is consistent with the laws of the United States and the United States Constitution.

### **BACKGROUND FACTS**

37. This case relates to the pioneering product Rituxan® and the duly-issued United States patents that cover the manufacture and use of that product. Rituxan® was the first monoclonal antibody approved by the FDA for therapeutic use in fighting cancer and is one of the most successful medicinal products in the world.

38. Plaintiffs are informed and believe, and on that basis allege, that (i) Sandoz is engaged in the development of a proposed biosimilar copy of Rituxan®, Rixathon/GP2013, (ii) the aBLA filed by Sandoz seeking FDA approval for Rixathon/GP2013 has named Rituxan® as the reference product that Rixathon/GP2013 is intended to copy, and (iii) the FDA has accepted Sandoz's aBLA for review.

39. Plaintiffs are informed and believe, and on that basis allege, that upon FDA approval Sandoz intends to import, market, distribute, offer to sell, and sell Rixathon/GP2013 in New Jersey and throughout the United States as an alleged biosimilar substitute for Rituxan®.

40. As alleged herein, the manufacture, importation, use, offer for sale, and/or sale of Rixathon/GP2013 infringes one or more patents owned or licensed by Plaintiffs, who therefore bring this patent action to address Sandoz's infringement and to protect the intellectual property into which they have invested innumerable resources, investments which have redounded to the benefit of the public and medicine in general.

**GENENTECH AND BIOGEN'S RITUXAN® PRODUCT**

41. Antibodies are produced by cells of the immune system and are an important component in the immune system's fight against foreign invaders, such as bacteria, viruses, and other microbes and pathogens. In particular, antibodies can bind (attach) to a specific molecular structure that can be present on such foreign invaders or can be present on the body's own cells. A structure to which an antibody binds is called an "antigen." By binding to specific antigens, antibodies help the immune system identify and attack the foreign invaders.

42. Although the human body creates antibodies for various antigens naturally, for several decades scientists have successfully engineered in laboratories antibodies capable of binding to a predetermined antigen, such that the antibodies can be used to develop therapeutic products that target specific medical conditions in humans.

43. In the early 1990s, after many years of research, IDEC Pharmaceuticals (which subsequently merged with Biogen) first created the antibody rituximab (then known as IDEC-C2B8). Researchers at IDEC Pharmaceuticals created rituximab in the laboratory to bind to the human CD20 antigen, a protein expressed on the surface of immune cells called B-cells. By binding to the CD20 antigen, rituximab helps to fight diseases caused or exacerbated by B-cells, including several forms of B-cell cancer.

44. Rituximab is a "chimeric" antibody, meaning that part of its structure is derived from human genetic sequence and part is derived from mouse genetic sequence. Creating this hybrid antibody and studying it in the laboratory, however, was only the beginning of the years-long process required to create an effective yet safe human therapeutic.

45. Following the creation of rituximab, IDEC Pharmaceuticals, Genentech, and F. Hoffmann-La Roche AG, in a tri-company collaboration, spent many years and many hundreds of millions of dollars on scientific studies and clinical trials to develop that therapeutic, which is marketed under the trade name Rituxan® in the United States and MabThera® abroad. They also dedicated enormous time and resources to establish the safety and efficacy of

Rituxan<sup>®</sup>, to investigate numerous ways to use Rituxan<sup>®</sup> to treat different diseases, and to determine how to manufacture Rituxan<sup>®</sup> in sufficient quantity and purity for administration to humans. For example, Rituxan<sup>®</sup> aids millions of patients in their fight against debilitating and life-threatening diseases, including Non-Hodgkin's Lymphomas (NHLs), Chronic Lymphocytic Leukemia (CLL), both of which are blood cancers, as well as Rheumatoid Arthritis (RA), and Vasculitis, both chronic and painful autoimmune diseases. Genentech and Biogen continue to dedicate significant time and resources to their ongoing efforts to maximize the effectiveness and use of Rituxan<sup>®</sup> to benefit patients across the world.

46. Because of its effectiveness against several diseases, including several forms of cancer, Rituxan<sup>®</sup>/MabThera<sup>®</sup> has been an enormous commercial success, generating over \$7 billion in worldwide revenue in 2016 alone.

47. The innovative work dedicated to creating and developing Rituxan<sup>®</sup> has been recognized repeatedly by the medical and scientific communities. For example, Rituxan<sup>®</sup> is on the World Health Organization's List of Essential Medicines (a well-recognized publication that identifies essential medicines for priority diseases) and Plaintiffs have been honored with the Trailblazers Award from the Cure for Lymphoma Foundation and with the Peter McCuen Cancer Research Award for their groundbreaking research and development of Rituxan<sup>®</sup>.

#### **THE BPCIA PATHWAY FOR BIOSIMILAR APPROVAL**

48. In 1984, Congress created an abbreviated regulatory pathway for the approval of generic small-molecule drugs through the passage of the Hatch-Waxman Act. Small molecule drugs are made from chemicals synthesized in a laboratory and contain both a relatively small number of atoms and a specific, known chemical structure. For example, the active ingredient in aspirin, acetylsalicylic acid, has only 21 atoms. Its chemical makeup and structure is easy to identify and characterize, and it is relatively simple to copy, develop, and manufacture.

49. Biologic agents, like the rituximab antibody in Rituxan<sup>®</sup>, are much larger and more complex molecules, and are not produced by chemical synthesis in a laboratory. Rather,

they are produced in, and purified from, specially modified living cells, making them extremely difficult to develop and manufacture. Whereas the small-molecule acetylsalicylic acid has only 21 atoms, a complex antibody biologic like rituximab contains about 20,000 atoms. Accordingly, the efforts and investment needed to develop a therapeutic antibody like Rituxan® are significantly greater than for a small-molecule drug like aspirin.

50. In contrast to the abbreviated regulatory pathway for generic small-molecule medicines provided in the Hatch-Waxman Act, no abbreviated pathway for approval of follow-on biologic products existed until the enactment in 2010 of the Biologics Price Competition and Innovation Act (“BPCIA”) (codified at 42 U.S.C. § 262) as part of the Patient Protection and Affordable Care Act. As a result, before the enactment of the BPCIA, the only way to obtain FDA approval of a biologic product was through an original Biologic License Application (“BLA”) supported by a full complement of pre-clinical and clinical study data. Genentech and Biogen underwent that long, laborious, and expensive process to obtain FDA approval for Rituxan®.

51. The BPCIA’s abbreviated pathway for biologic products requires a determination that the proposed product is “biosimilar” to a previously licensed “reference product.” 42 U.S.C. § 262(k). The BPCIA defines a “biosimilar” as a biological product that is (1) “highly similar to the reference product notwithstanding minor differences in clinically inactive components” and (2) has “no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.” 42 U.S.C. §§ 262(i)(2)(A), (B).

52. The BPCIA defines a “reference product” to be a “single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).” 42 U.S.C. § 262(i)(4). Here, Rituxan® is the reference product and Rixathon/GP2013 is the proposed biosimilar.

53. Under the BPCIA, biosimilar applicants are permitted to make use of the reference product sponsor’s proprietary safety and efficacy data and the FDA’s prior

determinations as to the safety, purity, and potency of the already-approved reference product. A biosimilar applicant must identify a single reference product that has already been approved by the FDA and submit to the FDA “publicly-available information regarding the Secretary’s previous determination that the reference product is safe, pure, and potent.” 42 U.S.C. § 262(k)(2)(A)(iii)(I).

54. Consequently, the abbreviated regulatory pathway created by the BPCIA allows a biosimilar applicant like Sandoz to avoid the time, expense, and risks of original research and development—as well as the need to conduct a full complement of pre-clinical and clinical testing—required for the submission of an original BLA. The abbreviated pathway thus permits a biosimilar applicant like Sandoz to gain approval to commercialize its biological product much more quickly than if it had undertaken the significant activities required for submission of an original BLA.

#### **SANDOZ’S DEVELOPMENT OF RIXATHON**

55. Plaintiffs are informed and believe, and on that basis allege, that on a date prior to September 12, 2017, Sandoz submitted to the FDA an aBLA for Rixathon/GP2013. On September 12, 2017, Sandoz issued a press release announcing that the FDA had accepted that aBLA for review. <https://www.sandoz.com/news/media-releases/sandoz-proposed-biosimilar-rituximab-accepted-review-fda>. More specifically, that press release stated that the FDA had “accepted [Sandoz’s] Biologics License Application (BLA) … for a proposed biosimilar to the reference medicine, Rituxan® (rituximab).” *Id.*

56. In addition, that same press release acknowledged that “Rituxan® is used to treat blood cancers including non-Hodgkin’s lymphoma (follicular lymphoma and diffuse large B-cell lymphoma) and chronic lymphocytic leukemia, as well as immunological diseases such as rheumatoid arthritis.” *Id.* These are diseases for which Rixathon was recently approved in Europe (as a biosimilar of rituximab marketed outside the United States under the trade name MabThera®). <https://www.novartis.com/news/media-releases/sandoz-receives-approval-europe->

[rixathonr-biosimilar-rituximab-treat-blood](#). Plaintiffs are informed and believe, and on that basis allege, that Sandoz is seeking FDA approval to treat those same diseases, i.e., those same “indications,” in the United States, thereby seeking FDA approval for a proposed biosimilar copying Rituxan® while intending to market that proposed biosimilar as a substitute treatment for the same medicinal purposes.

#### **THE BPCIA’S DISPUTE RESOLUTION PROCEDURES**

57. Although the BPCIA provides for an abbreviated regulatory pathway, it does not give biosimilar applicants like Sandoz the right to infringe validly issued patents through, *inter alia*, the manufacture, use, offer for sale, sale, or importation of a biologic product—even if approved by the FDA.

58. Recognizing that valid patents might preclude such activities, the BPCIA established a set of procedures for addressing patent disputes relating to prospective biosimilar products. These procedures are set forth in 42 U.S.C. § 262(l) and 35 U.S.C. § 271 and are intended to ensure that the innovator company whose product serves as the reference product has the opportunity to enforce its patent rights before a biosimilar product enters the market. The procedures are also intended to ensure that disputes over patent rights will take place in an orderly fashion, with the least possible uncertainty, brinksmanship, and burden on the parties and the courts.

59. The BPCIA dispute resolution procedure commences when a biosimilar application is accepted for review by the FDA. Within twenty days thereafter, the biosimilar applicant “shall provide” the reference sponsor with confidential access to “a copy of the [aBLA] submitted” to the FDA “and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.” 42 U.S.C. § 262(l)(2)(A).

60. After the applicant provides a copy of the aBLA and the required manufacturing information, the BPCIA contemplates a series of pre-litigation exchanges—including of a “list of

patents for which the reference sponsor believes a claim of patent infringement could reasonably be asserted by the reference sponsor” regarding the proposed biosimilar, *id.* at § 262(l)(3)(A)(i), and contentions regarding the alleged infringement, non-infringement, invalidity, and unenforceability of those patents, *id.* at § 262(l)(3)(B)—so that the parties may engage in good-faith negotiations over which patents should be litigated regarding the proposed biosimilar. *See id.* at § 262(l)(2)-(l)(6). These exchanges are colloquially referred to as the “Patent Dance.”

**SANDOZ’S DECISION NOT TO PARTICIPATE IN THE PATENT DANCE**

61. Sandoz has declined to participate in the Patent Dance.
62. Notwithstanding the detailed dispute resolution procedure set forth in the BPCIA, Sandoz informed Plaintiffs by letter dated September 28, 2017, that “Sandoz will not participate in the 42 U.S.C. § 262(l) patent information exchange process for [Rixathon] and, thereby, [will] forego the benefits available to it under that process.”
63. Instead, and in lieu of all “benefits available to it under” the Patent Dance, Sandoz agreed to provide Plaintiffs with access to the aBLA for Rixathon/GP2013 for a specified period of sixty (60) days and invited this litigation “on any patent that Genentech contends will be infringed by Sandoz’s proposed biosimilar product or by the use of such product.”
64. More than twenty days after being notified that the FDA had accepted its aBLA for review, Sandoz provided Genentech with access to its aBLA for Rixathon/GP2013. Specifically, on October 25, 2017, Sandoz provided outside counsel for Genentech with login credentials to remotely access the aBLA by agreement, not pursuant to any Patent Dance. Sandoz did not provide Plaintiffs with certain further “information that describes the process or processes used to manufacture” Rixathon/GP2013 required by 42 U.S.C. § 262(l)(2)(A).

65. Section 271(e)(2) of the Patent Act provides that if a biosimilar applicant “fails to provide the application and information required under” 42 U.S.C. § 262(l)(2)(A), as Sandoz has failed to do here, then it “shall be an act of infringement to submit … an application seeking

approval of a biological product for a patent that could have been identified pursuant" to the BPCIA's dispute resolution procedure.

**THE ASSERTED PATENTS**

66. Plaintiffs have applied for and obtained dozens of issued patents related to Rituxan®, including regarding its therapeutic uses, its administration, its formulation, and the processes by which it is manufactured.

67. Plaintiffs' ability to evaluate Sandoz's infringement of their patent estate has been hampered by Sandoz's decision not to provide, *inter alia*, manufacturing information as required by 42 U.S.C. § 262(l)(2)(A).

68. In light of the foregoing, and reserving all rights, Plaintiffs are informed and believe to the best of their present ability, and on that basis allege, that making, using, offering to sell, selling, or importing into the United States Rixathon/GP2013 will infringe, or reasonably could infringe, the following patents (collectively, the "Asserted Patents"), each of which is owned or exclusively licensed with the right to enforce by one or more Plaintiffs and, had Sandoz adhered to the BPCIA's dispute resolution procedure, could have been identified pursuant to that procedure:

• **U.S. Patent No. 6,121,428**

69. U.S. Patent No. 6,121,428 ("the '428 patent") is entitled "Protein Recovery," was duly and legally issued by the Patent Office on September 19, 2000, and has not expired.

70. One or more Plaintiffs have maintained the entire right, title, and interest in the '428 patent throughout the period of Sandoz's infringement. A copy of the '428 patent is attached as Exhibit 1.

• **U.S. Patent No. 6,331,415**

71. U.S. Patent No. 6,331,415 ("the '415 patent") is entitled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," was duly and legally issued by the Patent Office on December 18, 2001, and has not expired.

72. One or more Plaintiffs have maintained the entire right, title, and interest in the '415 patent throughout the period of Sandoz's infringement. A copy of the '415 patent is attached as Exhibit 2.

- **U.S. Patent No. 6,489,447**

73. U.S. Patent No. 6,489,447 ("the '447 patent") is entitled "Protein Purification," was duly and legally issued by the Patent Office on December 3, 2002, and has not expired.

74. One or more Plaintiffs have maintained the entire right, title, and interest in the '447 patent throughout the period of Sandoz's infringement. A copy of the '447 patent is attached as Exhibit 3.

- **U.S. Patent No. 6,610,516**

75. U.S. Patent No. 6,610,516 ("the '516 patent") is entitled "Cell Culture Process," was duly and legally issued by the Patent Office on August 26, 2003, and has not expired.

76. One or more Plaintiffs have maintained the entire right, title, and interest in the '516 patent throughout the period of Sandoz's infringement. A copy of the '516 patent is attached as Exhibit 4.

- **U.S. Patent No. 6,620,918**

77. U.S. Patent No. 6,620,918 ("the '918 patent") is entitled "Separation of Polypeptide Monomers," was duly and legally issued by the Patent Office on September 16, 2003, and has not expired.

78. One or more Plaintiffs have maintained the entire right, title, and interest in the '918 patent throughout the period of Sandoz's infringement. A copy of the '918 patent is attached as Exhibit 5.

- **U.S. Patent No. 6,870,034**

79. U.S. Patent No. 6,870,034 ("the '034 patent") is entitled "Protein Purification," was duly and legally issued by the Patent Office on March 22, 2005, and has not expired.

80. One or more Plaintiffs have maintained the entire right, title, and interest in the '034 patent throughout the period of Sandoz's infringement. A copy of the '034 patent is attached as Exhibit 6.

- **U.S. Patent No. 7,381,560**

81. U.S. Patent No. 7,381,560 ("the '560 patent") is entitled "Expression and Use of Anti-CD20 Antibodies," was duly and legally issued by the Patent Office on June 3, 2008, and has not expired.

82. One or more Plaintiffs have maintained the entire right, title, and interest in the '560 patent throughout the period of Sandoz's infringement. A copy of the '560 patent is attached as Exhibit 7.

- **U.S. Patent No. 7,485,704**

83. U.S. Patent No. 7,485,704 ("the '704 patent") is entitled "Reducing Protein A Leaching during Protein A Affinity Chromatography," was duly and legally issued by the Patent Office on February 3, 2009, and has not expired.

84. One or more Plaintiffs have maintained the entire right, title, and interest in the '704 patent throughout the period of Sandoz's infringement. A copy of the '704 patent is attached as Exhibit 8.

- **U.S. Patent No. 7,807,799**

85. U.S. Patent No. 7,807,799 ("the '799 patent") is entitled "Reducing Protein A Leaching during Protein A Affinity Chromatography," was duly and legally issued by the Patent Office on October 5, 2010, and has not expired.

86. One or more Plaintiffs have maintained the entire right, title, and interest in the '799 patent throughout the period of Sandoz's infringement. A copy of the '799 patent is attached as Exhibit 9.

- **U.S. Patent No. 7,820,161**

87. U.S. Patent No. 7,820,161 (“the ’161 patent”) is entitled “Treatment of Autoimmune Diseases,” was duly and legally issued by the Patent Office on October 26, 2010, and has not expired.

88. One or more Plaintiffs have maintained the entire right, title, and interest in the ’161 patent throughout the period of Sandoz’s infringement. A copy of the ’161 patent is attached as Exhibit 10.

- **U.S. Patent No. 7,923,221**

89. U.S. Patent No. 7,923,221 (“the ’221 patent”) is entitled “Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen,” was duly and legally issued by the Patent Office on April 12, 2011, and has not expired.

90. One or more Plaintiffs have maintained the entire right, title, and interest in the ’221 patent throughout the period of Sandoz’s infringement. A copy of the ’221 patent is attached as Exhibit 11.

- **U.S. Patent No. 7,976,838**

91. U.S. Patent No. 7,976,838 (“the ’838 patent”) is entitled “Therapy of Autoimmune Disease in a Patient with an Inadequate Response to a TNF- $\alpha$  inhibitor,” was duly and legally issued by the Patent Office on July 12, 2011, and has not expired.

92. One or more Plaintiffs have maintained the entire right, title, and interest in the ’838 patent throughout the period of Sandoz’s infringement. A copy of the ’838 patent is attached as Exhibit 12.

- **U.S. Patent No. 8,206,711**

93. U.S. Patent No. 8,206,711 (“the ’711 patent”) is entitled “Treatment of Chronic Lymphocytic Leukemia using Anti-CD20 Antibodies,” was duly and legally issued by the Patent Office on June 26, 2012, and has not expired.

94. One or more Plaintiffs have maintained the entire right, title, and interest in the '711 patent throughout the period of Sandoz's infringement. A copy of the '711 patent is attached as Exhibit 13.

- **U.S. Patent No. 8,314,225**

95. U.S. Patent No. 8,314,225 ("the '225 patent") is entitled "Heavy Chain Mutant Leading to Improved Immunoglobulin Production," was duly and legally issued by the Patent Office on November 20, 2012, and has not expired.

96. The '225 patent is assigned to Hoffmann-La Roche Inc., and Genentech is the exclusive licensee with the right to enforce the '225 patent. A copy of the '225 patent is attached as Exhibit 14.

- **U.S. Patent No. 8,329,172**

97. U.S. Patent No. 8,329,172 ("the '172 patent") is entitled "Combination Therapies for B-cell Lymphomas Comprising Administration of Anti-CD20 Antibody," was duly and legally issued by the Patent Office on December 11, 2012, and has not expired.

98. One or more Plaintiffs have maintained the entire right, title, and interest in the '172 patent throughout the period of Sandoz's infringement. A copy of the '172 patent is attached as Exhibit 15.

- **U.S. Patent No. 8,512,983**

99. U.S. Patent No. 8,512,983 ("the '983 patent") is entitled "Production of Proteins in Glutamine-free Cell Culture Media," was duly and legally issued by the Patent Office on August 20, 2013, and has not expired.

100. One or more Plaintiffs have maintained the entire right, title, and interest in the '983 patent throughout the period of Sandoz's infringement. A copy of the '983 patent is attached as Exhibit 16.

- **U.S. Patent No. 8,545,843**

101. U.S. Patent No. 8,545,843 (“the ’843 patent”) is entitled “Treatment of Vasculitis,” was duly and legally issued by the Patent Office on October 1, 2013, and has not expired.

102. One or more Plaintiffs have maintained the entire right, title, and interest in the ’843 patent throughout the period of Sandoz’s infringement. A copy of the ’843 patent is attached as Exhibit 17.

- **U.S. Patent No. 8,557,244**

103. U.S. Patent No. 8,557,244 (“the ’244 patent”) is entitled “Treatment of Aggressive Non-Hodgkins Lymphoma with Anti-CD20 Antibody,” was duly and legally issued by the Patent Office on October 15, 2013, and has not expired.

104. One or more Plaintiffs have maintained the entire right, title, and interest in the ’244 patent throughout the period of Sandoz’s infringement. A copy of the ’244 patent is attached as Exhibit 18.

- **U.S. Patent No. 8,574,869**

105. U.S. Patent No. 8,574,869 (“the ’869 patent”) is entitled “Prevention of Disulfide Bond Reduction during Recombinant Production of Polypeptides,” was duly and legally issued by the Patent Office on November 5, 2013, and has not expired.

106. One or more Plaintiffs have maintained the entire right, title, and interest in the ’869 patent throughout the period of Sandoz’s infringement. A copy of the ’869 patent is attached as Exhibit 19.

- **U.S. Patent No. 8,710,196**

107. U.S. Patent No. 8,710,196 (“the ’196 patent”) is entitled “Protein Purification,” was duly and legally issued by the Patent Office on April 29, 2014, and has not expired.

108. One or more Plaintiffs have maintained the entire right, title, and interest in the ’196 patent throughout the period of Sandoz’s infringement. A copy of the ’196 patent is attached as Exhibit 20.

- **U.S. Patent No. 8,821,873**

109. U.S. Patent No. 8,821,873 (“the ’873 patent”) is entitled “Treatment of Diffuse Large-cell Lymphoma with Anti-CD20 Antibody,” was duly and legally issued by the Patent Office on September 2, 2014, and has not expired.

110. One or more Plaintiffs have maintained the entire right, title, and interest in the ’873 patent throughout the period of Sandoz’s infringement. A copy of the ’873 patent is attached as Exhibit 21.

- **U.S. Patent No. 9,296,821**

111. U.S. Patent No. 9,296,821 (“the ’821 patent”) is entitled “Combination Therapies for B-cell Lymphomas Comprising Administration of Anti-CD20 Antibodies,” was duly and legally issued by the Patent Office on March 29, 2016, and has not expired.

112. One or more Plaintiffs have maintained the entire right, title, and interest in the ’821 patent throughout the period of Sandoz’s infringement. A copy of the ’821 patent is attached as Exhibit 22.

- **U.S. Patent No. 9,504,744**

113. U.S. Patent No. 9,504,744 (“the ’744 patent”) is entitled “Treatment of Diffuse Large-cell Lymphoma with Anti-CD20 Antibody,” was duly and legally issued by the Patent Office on November 29, 2016, and has not expired.

114. One or more Plaintiffs have maintained the entire right, title, and interest in the ’744 patent throughout the period of Sandoz’s infringement. A copy of the ’744 patent is attached as Exhibit 23.

- **U.S. Patent No. 9,714,293**

115. U.S. Patent No. 9,714,293 (“the ’293 patent”) is entitled “Production of Proteins in Glutamine-free Cell Culture Media,” was duly and legally issued by the Patent Office on July 25, 2017, and has not expired.

116. One or more Plaintiffs have maintained the entire right, title, and interest in the '293 patent throughout the period of Sandoz's infringement. A copy of the '293 patent is attached as Exhibit 24.

**COUNT I**

**(INFRINGEMENT OF U.S. PATENT NO. 6,121,428 UNDER 35 U.S.C. § 271(E)(2))**

117. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 116 as if fully set forth herein.

118. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

119. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

120. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

121. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

122. The '428 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

123. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

124. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '428 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

125. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '428 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

126. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '428 patent, with knowledge that the resulting conduct would infringe one or more claims of the '428 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '428 patent.

127. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '428 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

128. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

129. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '428 patent. *See* 35 U.S.C. § 271(e)(4)(B).

130. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '428 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

131. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '428 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

## COUNT II

### **(INFRINGEMENT OF U.S. PATENT NO. 6,331,415 UNDER 35 U.S.C. § 271(E)(2))**

132. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 131 as if fully set forth herein.

133. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

134. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

135. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and

when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

136. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

137. The '415 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

138. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

139. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '415 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

140. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '415 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers,

distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

141. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '415 patent, with knowledge that the resulting conduct would infringe one or more claims of the '415 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '415 patent.

142. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '415 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

143. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

144. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '415 patent. *See* 35 U.S.C. § 271(e)(4)(B).

145. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '415 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

146. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '415 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs

incurred under 35 U.S.C. § 285.

**COUNT III**

**(INFRINGEMENT OF U.S. PATENT NO. 6,489,447 UNDER 35 U.S.C. § 271(E)(2))**

147. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 146 as if fully set forth herein.

148. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

149. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

150. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

151. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

152. The '447 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

153. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological

product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

154. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '447 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

155. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '447 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

156. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '447 patent, with knowledge that the resulting conduct would infringe one or more claims of the '447 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '447 patent.

157. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '447 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

158. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

159. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '447 patent. *See* 35 U.S.C. § 271(e)(4)(B).

160. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '447 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

161. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '447 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

#### **COUNT IV**

##### **(INFRINGEMENT OF U.S. PATENT NO. 6,610,516 UNDER 35 U.S.C. § 271(E)(2))**

162. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 161 as if fully set forth herein.

163. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

164. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

165. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

166. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

167. The '516 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

168. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

169. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '516 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

170. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '516 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

171. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '516 patent, with knowledge that the resulting conduct would infringe one or more claims of the '516 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '516 patent.

172. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '516 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

173. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

174. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '516 patent. *See* 35 U.S.C. § 271(e)(4)(B).

175. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '516 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

176. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '516 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT V**

**(INFRINGEMENT OF U.S. PATENT NO. 6,620,918 UNDER 35 U.S.C. § 271(E)(2))**

177. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 176 as if fully set forth herein.

178. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

179. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

180. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

181. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

182. The '918 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

183. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological

product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

184. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '918 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

185. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '918 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

186. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '918 patent, with knowledge that the resulting conduct would infringe one or more claims of the '918 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '918 patent.

187. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '918 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

188. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

189. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '918 patent. *See* 35 U.S.C. § 271(e)(4)(B).

190. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '918 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

191. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '918 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

## **COUNT VI**

### **(INFRINGEMENT OF U.S. PATENT NO. 6,870,034 UNDER 35 U.S.C. § 271(E)(2))**

192. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 191 as if fully set forth herein.

193. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

194. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

195. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

196. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

197. The '034 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

198. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

199. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '034 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

200. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '034 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

201. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '034 patent, with knowledge that the resulting conduct would infringe one or more claims of the '034 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '034 patent.

202. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '034 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

203. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

204. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '034 patent. *See* 35 U.S.C. § 271(e)(4)(B).

205. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '034 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

206. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '034 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT VII**

**(INFRINGEMENT OF U.S. PATENT NO. 7,381,560 UNDER 35 U.S.C. § 271(E)(2))**

207. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 206 as if fully set forth herein.

208. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

209. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

210. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

211. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

212. The '560 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

213. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological

product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

214. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '560 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

215. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '560 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

216. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '560 patent, with knowledge that the resulting conduct would infringe one or more claims of the '560 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '560 patent.

217. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '560 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

218. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

219. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '560 patent. *See* 35 U.S.C. § 271(e)(4)(B).

220. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '560 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

221. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '560 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

### **COUNT VIII**

#### **(INFRINGEMENT OF U.S. PATENT NO. 7,485,704 UNDER 35 U.S.C. § 271(E)(2))**

222. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 221 as if fully set forth herein.

223. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

224. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

225. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

226. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

227. The '704 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

228. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

229. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '704 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

230. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '704 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

231. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '704 patent, with knowledge that the resulting conduct would infringe one or more claims of the '704 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '704 patent.

232. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '704 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

233. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

234. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '704 patent. *See* 35 U.S.C. § 271(e)(4)(B).

235. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '704 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

236. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '704 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT IX**

**(INFRINGEMENT OF U.S. PATENT NO. 7,807,799 UNDER 35 U.S.C. § 271(E)(2))**

237. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 236 as if fully set forth herein.

238. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

239. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

240. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

241. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

242. The '799 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

243. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological

product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

244. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '799 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

245. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '799 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

246. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '799 patent, with knowledge that the resulting conduct would infringe one or more claims of the '799 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '799 patent.

247. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '799 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

248. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

249. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '799 patent. *See* 35 U.S.C. § 271(e)(4)(B).

250. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '799 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

251. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '799 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

## **COUNT X**

### **(INFRINGEMENT OF U.S. PATENT NO. 7,820,161 UNDER 35 U.S.C. § 271(E)(2))**

252. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 251 as if fully set forth herein.

253. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

254. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

255. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

256. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

257. The '161 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

258. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

259. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '161 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

260. Moreover, the '161 patent covers certain uses of rituximab for the treatment of Rheumatoid Arthritis. Plaintiffs are informed and believe, and on that basis allege, that Sandoz specifically intends to, among other things, market and sell Rixathon/GP2013 for the express purpose of treating Rheumatoid Arthritis.

261. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '161 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*,

encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

262. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '161 patent, with knowledge that the resulting conduct would infringe one or more claims of the '161 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '161 patent.

263. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '161 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

264. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

265. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '161 patent. *See* 35 U.S.C. § 271(e)(4)(B).

266. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '161 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

267. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '161 patent justifies an injunction and an award to

Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT XI**

**(INFRINGEMENT OF U.S. PATENT NO. 7,923,221 UNDER 35 U.S.C. § 271(E)(2))**

268. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 267 as if fully set forth herein.

269. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

270. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

271. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

272. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

273. The '221 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

274. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

275. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '221 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

276. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '221 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

277. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '221 patent, with knowledge that the resulting conduct would infringe one or more claims of the '221 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '221 patent.

278. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '221 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

279. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

280. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '221 patent. *See* 35 U.S.C. § 271(e)(4)(B).

281. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '221 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

282. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '221 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

## COUNT XII

### **(INFRINGEMENT OF U.S. PATENT NO. 7,976,838 UNDER 35 U.S.C. § 271(E)(2))**

283. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 282 as if fully set forth herein.

284. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

285. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

286. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and

when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

287. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

288. The '838 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

289. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

290. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '838 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

291. Moreover, the '838 patent covers certain uses of rituximab for the treatment of Rheumatoid Arthritis. Plaintiffs are informed and believe, and on that basis allege, that Sandoz specifically intends to, among other things, market and sell Rixathon/GP2013 for the express purpose of treating Rheumatoid Arthritis.

292. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '838 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

293. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '838 patent, with knowledge that the resulting conduct would infringe one or more claims of the '838 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '838 patent.

294. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '838 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

295. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

296. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '838 patent. *See* 35 U.S.C. § 271(e)(4)(B).

297. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '838 patent and its infringement thereof, Sandoz willfully, wantonly, and

deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

298. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '838 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT XIII**

**(INFRINGEMENT OF U.S. PATENT NO. 8,206,711 UNDER 35 U.S.C. § 271(E)(2))**

299. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 298 as if fully set forth herein.

300. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

301. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

302. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

303. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

304. The '711 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

305. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

306. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '711 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

307. Moreover, the '711 patent covers certain uses of rituximab for the treatment of Chronic Lymphocytic Leukemia. Plaintiffs are informed and believe, and on that basis allege, that Sandoz specifically intends to, among other things, market and sell Rixathon/GP2013 for the express purpose of treating Chronic Lymphocytic Leukemia.

308. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '711 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

309. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '711 patent, with

knowledge that the resulting conduct would infringe one or more claims of the '711 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '711 patent.

310. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '711 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

311. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

312. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '711 patent. *See* 35 U.S.C. § 271(e)(4)(B).

313. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '711 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

314. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '711 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT XIV**

**(INFRINGEMENT OF U.S. PATENT NO. 8,314,225 UNDER 35 U.S.C. § 271(E)(2))**

315. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 314 as if fully set forth herein.

316. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

317. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

318. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

319. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

320. The '225 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

321. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological

product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

322. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '225 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

323. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '225 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

324. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '225 patent, with knowledge that the resulting conduct would infringe one or more claims of the '225 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '225 patent.

325. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '225 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

326. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

327. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '225 patent. *See* 35 U.S.C. § 271(e)(4)(B).

328. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '225 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

329. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '225 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

#### COUNT XV

##### **(INFRINGEMENT OF U.S. PATENT NO. 8,329,172 UNDER 35 U.S.C. § 271(E)(2))**

330. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 329 as if fully set forth herein.

331. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

332. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

333. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

334. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

335. The '172 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

336. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

337. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '172 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

338. Moreover, the '172 patent covers certain uses of rituximab for the treatment of Non-Hodgkin's Lymphoma. Plaintiffs are informed and believe, and on that basis allege, that Sandoz specifically intends to, among other things, market and sell Rixathon/GP2013 for the express purpose of treating Non-Hodgkin's Lymphoma.

339. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '172 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*,

encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

340. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '172 patent, with knowledge that the resulting conduct would infringe one or more claims of the '172 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '172 patent.

341. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '172 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

342. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

343. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '172 patent. *See* 35 U.S.C. § 271(e)(4)(B).

344. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '172 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

345. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '172 patent justifies an injunction and an award to

Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT XVI**

**(INFRINGEMENT OF U.S. PATENT NO. 8,512,983 UNDER 35 U.S.C. § 271(E)(2))**

346. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 345 as if fully set forth herein.

347. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

348. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

349. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

350. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

351. The '983 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

352. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

353. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '983 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

354. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '983 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

355. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '983 patent, with knowledge that the resulting conduct would infringe one or more claims of the '983 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '983 patent.

356. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '983 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

357. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

358. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '983 patent. *See* 35 U.S.C. § 271(e)(4)(B).

359. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '983 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

360. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '983 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

### **COUNT XVII**

#### **(INFRINGEMENT OF U.S. PATENT NO. 8,545,843 UNDER 35 U.S.C. § 271(E)(2))**

361. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 360 as if fully set forth herein.

362. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

363. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

364. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and

when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

365. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

366. The '843 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

367. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

368. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '843 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

369. Moreover, the '843 patent covers certain uses of rituximab for the treatment of Vasculitis. Plaintiffs are informed and believe, and on that basis allege, that Sandoz specifically intends to, among other things, market and sell Rixathon/GP2013 for the express purpose of treating Vasculitis.

370. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '843 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

371. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '843 patent, with knowledge that the resulting conduct would infringe one or more claims of the '843 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '843 patent.

372. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '843 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

373. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

374. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '843 patent. *See* 35 U.S.C. § 271(e)(4)(B).

375. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '843 patent and its infringement thereof, Sandoz willfully, wantonly, and

deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

376. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '843 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT XVIII**

**(INFRINGEMENT OF U.S. PATENT NO. 8,557,244 UNDER 35 U.S.C. § 271(E)(2))**

377. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 376 as if fully set forth herein.

378. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

379. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

380. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

381. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

382. The '244 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

383. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

384. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '244 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

385. Moreover, the '244 patent covers certain uses of rituximab for the treatment of Diffuse Large Cell Lymphoma. Plaintiffs are informed and believe, and on that basis allege, that Sandoz specifically intends to, among other things, market and sell Rixathon/GP2013 for the express purpose of treating Diffuse Large Cell Lymphoma.

386. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '244 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

387. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '244 patent, with

knowledge that the resulting conduct would infringe one or more claims of the '244 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '244 patent.

388. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '244 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

389. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

390. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '244 patent. *See* 35 U.S.C. § 271(e)(4)(B).

391. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '244 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

392. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '244 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT XIX**

**(INFRINGEMENT OF U.S. PATENT NO. 8,574,869 UNDER 35 U.S.C. § 271(E)(2))**

393. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 392 as if fully set forth herein.

394. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

395. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

396. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

397. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

398. The '869 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

399. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological

product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

400. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '869 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

401. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '869 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

402. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '869 patent, with knowledge that the resulting conduct would infringe one or more claims of the '869 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '869 patent.

403. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '869 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

404. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

405. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '869 patent. *See* 35 U.S.C. § 271(e)(4)(B).

406. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '869 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

407. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '869 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT XX**

**(INFRINGEMENT OF U.S. PATENT NO. 8,710,196 UNDER 35 U.S.C. § 271(E)(2))**

408. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 407 as if fully set forth herein.

409. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

410. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

411. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

412. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

413. The '196 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

414. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

415. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '196 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

416. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '196 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

417. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '196 patent, with knowledge that the resulting conduct would infringe one or more claims of the '196 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '196 patent.

418. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '196 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

419. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

420. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '196 patent. *See* 35 U.S.C. § 271(e)(4)(B).

421. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '196 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

422. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '196 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT XXI**

**(INFRINGEMENT OF U.S. PATENT NO. 8,821,873 UNDER 35 U.S.C. § 271(E)(2))**

423. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 422 as if fully set forth herein.

424. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

425. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

426. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

427. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

428. The '873 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

429. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological

product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

430. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '873 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

431. Moreover, the '873 patent covers certain uses of rituximab for the treatment of Diffuse Large Cell Lymphoma. Plaintiffs are informed and believe, and on that basis allege, that Sandoz specifically intends to, among other things, market and sell Rixathon/GP2013 for the express purpose of treating Diffuse Large Cell Lymphoma.

432. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '873 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

433. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '873 patent, with knowledge that the resulting conduct would infringe one or more claims of the '873 patent, and with the specific intent that the resulting conduct of Sandoz infringe one or more claims of the '873 patent.

434. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '873 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by

numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

435. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

436. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '873 patent. *See* 35 U.S.C. § 271(e)(4)(B).

437. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '873 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

438. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '873 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

## **COUNT XXII**

### **(INFRINGEMENT OF U.S. PATENT NO. 9,296,821 UNDER 35 U.S.C. § 271(E)(2))**

439. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 438 as if fully set forth herein.

440. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

441. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

442. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

443. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

444. The '821 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

445. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

446. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '821 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

447. Moreover, the '821 patent covers certain uses of rituximab for the treatment of Non-Hodgkin's Lymphoma. Plaintiffs are informed and believe, and on that basis allege, that Sandoz specifically intends to, among other things, market and sell Rixathon/GP2013 for the express purpose of treating Non-Hodgkin's Lymphoma.

448. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '821 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

449. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '821 patent, with knowledge that the resulting conduct would infringe one or more claims of the '821 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '821 patent.

450. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '821 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

451. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

452. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or

participation with it, is enjoined from any and all activities that would infringe the claims of the '821 patent. *See* 35 U.S.C. § 271(e)(4)(B).

453. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '821 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

454. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '821 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

### **COUNT XXIII**

#### **(INFRINGEMENT OF U.S. PATENT NO. 9,504,744 UNDER 35 U.S.C. § 271(E)(2))**

455. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 454 as if fully set forth herein.

456. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

457. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

458. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

459. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

460. The '744 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

461. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,  
if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."

462. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '744 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

463. Moreover, the '744 patent covers certain uses of rituximab for the treatment of Diffuse Large Cell Lymphoma. Plaintiffs are informed and believe, and on that basis allege, that Sandoz specifically intends to, among other things, market and sell Rixathon/GP2013 for the express purpose of treating Diffuse Large Cell Lymphoma.

464. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '744 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers,

distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

465. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '744 patent, with knowledge that the resulting conduct would infringe one or more claims of the '744 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '744 patent.

466. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '744 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

467. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

468. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '744 patent. *See* 35 U.S.C. § 271(e)(4)(B).

469. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '744 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

470. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '744 patent justifies an injunction and an award to

Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

**COUNT XXIV**

**(INFRINGEMENT OF U.S. PATENT NO. 9,714,293 UNDER 35 U.S.C. § 271(E)(2))**

471. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 470 as if fully set forth herein.

472. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has submitted an aBLA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Rixathon/GP2013, a proposed biosimilar version of Rituxan®.

473. Plaintiffs are informed and believe, and on that basis allege, that the FDA accepted Sandoz's aBLA for review on or about September 12, 2017.

474. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

475. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has failed to provide the information required under 42 U.S.C. § 262(l)(2)(A).

476. The '293 patent could have been identified pursuant to the BPCIA's dispute resolution procedure, specifically through 42 U.S.C. § 262(l)(3).

477. Pursuant to 35 U.S.C. § 271(e)(2)(c), "it shall be an act of infringement to submit...:

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.”

478. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has infringed one or more claims of the '293 patent under 35 U.S.C. § 271(e)(2)(c) by filing its aBLA for Rixathon/GP2013 for the express purpose of making, using, offering for sale, selling, and/or importing Rixathon/GP2013 upon approval without license or authority from Plaintiffs, which activities would be in violation of 35 U.S.C. § 271, literally and/or under the doctrine of equivalents.

479. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has further infringed, or will further infringe, the '293 patent by actively inducing infringement of one or more claims of that patent, literally and/or under the doctrine of equivalents, by, *inter alia*, encouraging, instructing, and directing one or more subsidiaries, licensees, co-marketers, distributors, physicians, and/or other third parties to, among other things, make, use, offer for sale, sell, and/or import Rixathon/GP2013 without license or authority from Plaintiffs.

480. Plaintiffs are informed and believe, and on that basis allege, that Sandoz has engaged and continues to engage in these acts with knowledge of the '293 patent, with knowledge that the resulting conduct would infringe one or more claims of the '293 patent, and with the specific intent that the resulting conduct infringe one or more claims of the '293 patent.

481. For example, Plaintiffs are informed and believe, and on that basis allege, that Sandoz has knowledge of and is aware of the '293 patent, including because Sandoz has extensively monitored Plaintiffs' Rituxan® patent estate for several years, as evidenced by numerous legal proceedings, including *inter partes* reviews, relating to Plaintiffs' Rituxan® patent rights in which Sandoz has participated in the United States and worldwide.

482. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty. *See* 35 U.S.C. § 271(e)(4)(C); 35 U.S.C. § 284.

483. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy, unless Sandoz, together with each person and entity acting on its behalf or in active concert or participation with it, is enjoined from any and all activities that would infringe the claims of the '293 patent. *See* 35 U.S.C. § 271(e)(4)(B).

484. Plaintiffs are informed and believe, and on that basis allege, that despite Sandoz's knowledge of the '293 patent and its infringement thereof, Sandoz willfully, wantonly, and deliberately engaged in the acts of infringement alleged herein, either individually or through the approval, direction, and control of others.

485. Plaintiffs are informed and believe, and on that basis allege, that Sandoz's willful, wanton, and deliberate infringement of the '293 patent justifies an injunction and an award to Plaintiffs of enhanced damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

#### COUNT XXV

#### **(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,121,428)**

486. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 485 as if fully set forth herein.

487. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

488. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

489. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale,

and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '428 patent.

490. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

491. The '428 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

492. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '428 patent.

493. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

494. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '428 patent.

#### **COUNT XXVI**

#### **(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,331,415)**

495. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 494 as if fully set forth herein.

496. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

497. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

498. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '415 patent.

499. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

500. The '415 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

501. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '415 patent.

502. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

503. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '415 patent.

**COUNT XXVII**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,489,447)**

504. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 503 as if fully set forth herein.

505. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

506. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

507. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '447 patent.

508. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

509. The '447 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

510. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '447 patent.

511. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

512. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '447 patent.

**COUNT XXVIII**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,610,516)**

513. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 512 as if fully set forth herein.

514. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

515. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

516. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '516 patent.

517. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

518. The '516 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

519. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '516 patent.

520. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

521. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '516 patent.

#### **COUNT XXIX**

##### **(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,620,918)**

522. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 521 as if fully set forth herein.

523. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

524. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

525. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '918 patent.

526. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with “information that describes the process or processes used to manufacture” Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to “bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”

527. The '918 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

528. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '918 patent.

529. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

530. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '918 patent.

### **COUNT XXX**

#### **(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,870,034)**

531. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 530 as if fully set forth herein.

532. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

533. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and

when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

534. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '034 patent.

535. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with “information that describes the process or processes used to manufacture” Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to “bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”

536. The '034 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

537. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '034 patent.

538. Sandoz’s infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

539. Moreover, Sandoz’s infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '034 patent.

**COUNT XXXI**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,381,560)**

540. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 539 as if fully set forth herein.

541. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

542. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

543. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '560 patent.

544. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

545. The '560 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

546. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '560 patent.

547. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

548. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '560 patent.

**COUNT XXXII**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,485,704)**

549. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 548 as if fully set forth herein.

550. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

551. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

552. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '704 patent.

553. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

554. The '704 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

555. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '704 patent.

556. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

557. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '704 patent.

### **COUNT XXXIII**

#### **(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,807,799)**

558. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 557 as if fully set forth herein.

559. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

560. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

561. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '799 patent.

562. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with “information that describes the process or processes used to manufacture” Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to “bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”

563. The '799 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

564. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '799 patent.

565. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

566. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '799 patent.

#### COUNT XXXIV

#### **(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,820,161)**

567. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 566 as if fully set forth herein.

568. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

569. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and

when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

570. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '161 patent.

571. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with “information that describes the process or processes used to manufacture” Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to “bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”

572. The '161 patent claims the biological product or a use of the biological product at issue in this action: Rituxan®.

573. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '161 patent.

574. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

575. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '161 patent.

**COUNT XXXV**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,923,221)**

576. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 575 as if fully set forth herein.

577. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

578. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

579. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '221 patent.

580. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

581. The '221 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

582. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '221 patent.

583. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

584. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '221 patent.

**COUNT XXXVI**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,976,838)**

585. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 584 as if fully set forth herein.

586. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

587. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

588. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '838 patent.

589. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

590. The '838 patent claims the biological product or a use of the biological product at issue in this action: Rituxan®.

591. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '838 patent.

592. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

593. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '838 patent.

### **COUNT XXXVII**

#### **(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,206,711)**

594. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 593 as if fully set forth herein.

595. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

596. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

597. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '711 patent.

598. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with “information that describes the process or processes used to manufacture” Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to “bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”

599. The '711 patent claims the biological product or a use of the biological product at issue in this action: Rituxan®.

600. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '711 patent.

601. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

602. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '711 patent.

### **COUNT XXXVIII**

#### **(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,314,225)**

603. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 602 as if fully set forth herein.

604. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

605. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and

when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

606. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '225 patent.

607. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with “information that describes the process or processes used to manufacture” Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to “bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”

608. The '225 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

609. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '225 patent.

610. Sandoz’s infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

611. Moreover, Sandoz’s infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '225 patent.

**COUNT XXXIX**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,329,172)**

612. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 611 as if fully set forth herein.

613. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

614. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

615. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '172 patent.

616. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

617. The '172 patent claims the biological product or a use of the biological product at issue in this action: Rituxan®.

618. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '172 patent.

619. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

620. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '172 patent.

**COUNT XL**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,512,983)**

621. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 620 as if fully set forth herein.

622. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

623. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

624. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '983 patent.

625. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

626. The '983 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

627. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '983 patent.

628. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

629. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '983 patent.

#### **COUNT XLI**

##### **(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,545,843)**

630. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 629 as if fully set forth herein.

631. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

632. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

633. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '843 patent.

634. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with “information that describes the process or processes used to manufacture” Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to “bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”

635. The '843 patent claims the biological product or a use of the biological product at issue in this action: Rituxan®.

636. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '843 patent.

637. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

638. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '843 patent.

#### **COUNT XLII**

#### **(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,557,244)**

639. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 638 as if fully set forth herein.

640. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

641. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and

when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

642. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '244 patent.

643. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with “information that describes the process or processes used to manufacture” Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to “bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”

644. The '244 patent claims the biological product or a use of the biological product at issue in this action: Rituxan®.

645. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '244 patent.

646. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

647. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '244 patent.

**COUNT XLIII**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,574,869)**

648. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 647 as if fully set forth herein.

649. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

650. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

651. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '869 patent.

652. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

653. The '869 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

654. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '869 patent.

655. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

656. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '869 patent.

**COUNT XLIV**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,710,196)**

657. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 656 as if fully set forth herein.

658. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

659. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

660. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '196 patent.

661. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

662. The '196 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

663. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '196 patent.

664. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

665. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '196 patent.

**COUNT XLV**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,821,873)**

666. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 665 as if fully set forth herein.

667. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

668. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

669. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '873 patent.

670. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with “information that describes the process or processes used to manufacture” Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to “bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”

671. The '873 patent claims the biological product or a use of the biological product at issue in this action: Rituxan®.

672. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '873 patent.

673. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

674. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '873 patent.

#### **COUNT XLVI**

#### **(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,296,821)**

675. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 674 as if fully set forth herein.

676. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

677. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and

when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

678. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '821 patent.

679. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with “information that describes the process or processes used to manufacture” Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to “bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.”

680. The '821 patent claims the biological product or a use of the biological product at issue in this action: Rituxan®.

681. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '821 patent.

682. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

683. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '821 patent.

**COUNT XLVII**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,504,744)**

684. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 683 as if fully set forth herein.

685. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

686. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

687. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '744 patent.

688. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

689. The '744 patent claims the biological product or a use of the biological product at issue in this action: Rituxan®.

690. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '744 patent.

691. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

692. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '744 patent.

**COUNT XLVIII**

**(DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,714,293)**

693. Plaintiffs re-allege and incorporate the allegations in Paragraphs 1 through 692 as if fully set forth herein.

694. The FDA has publicly stated that the agency's goal is to act upon an aBLA application within 10 months of receipt.

695. Plaintiffs are informed and believe, and on that basis allege, that Sandoz intends to engage in the commercial manufacture, use, offer for sale, and sale of Rixathon/GP2013 if and when it receives FDA approval to do so, as well as to import Rixathon/GP2013 into the United States for those purposes.

696. An actual, substantial, and justiciable controversy has arisen and now exists between the parties concerning whether, *inter alia*, the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the '293 patent.

697. On account of its decision not to engage in the Patent Dance, Sandoz has not complied with the requirements of 42 U.S.C. § 262(l)(2)(A) by failing to provide Plaintiffs with "information that describes the process or processes used to manufacture" Rixathon/GP2013. As a result, Plaintiffs are entitled under 42 U.S.C. § 262(l)(9)(C) to "bring an action under section 2201 of Title 28, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product."

698. The '293 patent claims methods of making a therapeutic antibody product such as Rixathon/GP2013.

699. Plaintiffs are entitled to a judicial declaration that Sandoz has or will infringe, directly and/or indirectly, literally and/or under the doctrine of equivalents, one or more claims of the '293 patent.

700. Sandoz's infringement has and will continue to damage Plaintiffs, who are entitled to recover jointly or severally from Defendants the damages resulting from Sandoz's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

701. Moreover, Sandoz's infringement has caused, and will continue to cause, irreparable injury to Plaintiffs, injury for which damages are an inadequate remedy unless Sandoz, together with, *inter alia*, all subsidiaries, partners, co-marketers, and licensees, is enjoined from any and all activities that would infringe the claims of the '293 patent.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for relief as follows:

- A. Judgment that Sandoz has infringed one or more claims of the Asserted Patents, directly and/or indirectly, literally and/or under the doctrine of equivalents;
- B. An award of damages pursuant to 35 U.S.C. § 271(e)(4)(C) and 35 U.S.C. § 284;
- C. A declaration that the manufacture, use, offer for sale, sale, and/or importation of Rixathon/GP2013 has or will infringe one or more claims of the Asserted Patents;
- D. A declaration that the Asserted Patents are valid and enforceable;
- E. A judgment that Sandoz's infringement was willful and deliberate, an injunction, and a three-fold increase in the award of any damages in accordance with 35 U.S.C. § 284;
- F. An award for an accounting of damages from Sandoz's infringement;
- G. Preliminary and/or permanent injunctive relief, including pursuant to 35 U.S.C. § 271(e)(4)(B), including an order that Sandoz and any of its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting

for any of them and/or on any of their behalf, and other persons in active concert or participation with any of them directly and/or indirectly, be preliminarily and permanently enjoined from infringing, inducing others to infringe, or contributing to the infringement of the Asserted Patents;

H. An award to Plaintiffs of their costs and reasonable expenses to the fullest extent permitted by law;

I. A declaration that this case is exceptional pursuant to 35 U.S.C. § 285, and an award of attorneys' fees and costs pursuant to 35 U.S.C. § 285 and 35 U.S.C. § 271(e)(4); and

J. An award of such other and further relief as the Court may deem just and proper.

**JURY DEMAND**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs hereby demand trial by jury of all issues so triable by a jury in this action.

Dated: December 21, 2017	By: <u>/s/ Keith J. Miller</u> Keith J. Miller, Esq. ROBINSON MILLER LLC One Newark Center, 19th Floor Newark, NJ 07102 Telephone: (973) 690-5400 kmiller@rwmlegal.com
<i>Of Counsel:</i>  David I. Gindler Gary N. Frischling Keith A. Orso IRELL & MANELLA LLP 1800 Avenue of the Stars, Suite 900 Los Angeles, CA 90067 Telephone: (310) 277-1010	<i>Attorneys for Plaintiffs Genentech, Inc., Biogen, Inc., and City of Hope</i>

**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Plaintiffs, by their undersigned counsel, hereby certify that the matter in controversy in this case is not the subject of any action pending in any court, or of any pending arbitration or administrative proceeding, except for the following *inter partes* review proceedings, which involve one or more of the parties and/or certain of the patents asserted in the instant case:

- IPR No. 2016-01614
- IPR No. 2016-01837
- IPR No. 2017-01115
- IPR No. 2017-01923
- IPR No. 2017-02036
- IPR No. 2017-02042
- IPR No. 2017-01095
- IPR No. 2017-01166
- IPR No. 2017-01167
- IPR No. 2017-01168
- IPR No. 2017-02127

Dated: December 21, 2017  <i>Of Counsel:</i>  David I. Gindler Gary N. Frischling Keith A. Orso IRELL & MANELLA LLP 1800 Avenue of the Stars, Suite 900 Los Angeles, CA 90067 Telephone: (310) 277-1010	By: <u>/s/ Keith J. Miller</u> Keith J. Miller, Esq. ROBINSON MILLER LLC One Newark Center, 19th Floor Newark, NJ 07102 Telephone: (973) 690-5400 kmiller@rwmlegal.com  <i>Attorneys for Plaintiffs Genentech, Inc., Biogen, Inc., and City of Hope</i>
---	---